

**REMARKS**

These remarks are in response to the Office Action mailed February 20, 2004. Support for the amendments to claims 1, 25 and 26 can be found in the specification (e.g., for the EGM2MV media, the amendment identifies the chemical character of the medium by using scientific language, see MPEP §608.01(v)) and in original claim 14. Accordingly, no new matter has been added and entry of the amendment is respectfully requested.

Further, the Examiner has not made clear the disposition of all of the claims relative to the cited art. For example, while the Office Action recites that “[c]laims 9, 10, 14, and 22-32 appear to be free of the art of record,” analysis of the claims allegedly rejected in view of the art cited would suggest that in addition to the claims, *supra*, claims 17-21 are also free of the cited art, since the latter claims were not rejected in view of said art. Applicants respectfully request clarification of this issue.

**I. The Restriction Requirement**

Applicants' election of Group I and traversal were acknowledged. However, the Office Action alleges that because Applicants did not specifically point out errors in the restriction requirement, the election was treated as not being traversed.

**II. Rejection Under 35 U.S.C. §112 Second Paragraph**

Claims 1-32 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants traverse the rejection against these claims, including those claims as amended, for the reasons given below.

The Office Action states that the metes and bounds of the term “embryoid body derived cell culture” are not clear. However, the term “embryoid body” is a term of art, moreover, the term has been in use since at least 1960 (e.g., Stevens et al., (1960) *Embryonic Potency of*

Embryoid Bodies Derived from a Transplantable Testicular Teratoma of the Mouse. *Dev Biol.* 2:285-97). Further, the term is defined in the specification at page 10, lines 17-20.

The plain meaning for the word "derived" is to "a: take, receive, or obtain especially from a specified source; b: to obtain (a chemical substance) actually or theoretically from a parent substance." (See, <<http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=derived>>, last visited, April 30, 2004). Therefore, one of skill in the art would know that the cell culture as originally claimed is made up of cells taken from embryoid bodies (i.e., a specified source).

The examples offered by the Examiner are inapposite because a primary culture of a particular tissue would be derived from that tissue (e.g., muscle tissue derived cell culture). The culture as claimed is derived from embryoid bodies, thus, the culture is obtained from that particular source.

As such, because one of skill in the art would know where the cell culture is to be obtained from, the skilled artisan would know the metes and bounds of the invention as originally claimed.

The Action goes on to state that as claims 25 and 26 contain the trademark/trade name EGM2MV, the claims are indefinite, citing Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). While not acquiescing to the reasoning offered by the Examiner and to place the application in better condition for allowance, Applicants have amended the claims to identify the constituents of EGM2MV. Moreover, Applicants have provided, for the convenience of the Examiner, a product information document for EGM2MV as Exhibit A.

For the reasons given above, Applicants respectfully submit that the rejection does not apply to the claims, including those as amended, and request that the rejection be withdrawn.

### **III. Rejection Under 35 U.S.C. §102(b)**

Claims 1, 2, 7, 11 and 12 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Shambrott et al (1998). Applicants traverse the rejection against these claims, including those as amended, for the reasons given below.

Shambrott et al. is alleged to teach the formation of embryoid bodies. In addition, the Action alleges that as further culture of the embryoid bodies would produce additional embryoid bodies from the nascent embryoid body (EB), the additional embryoid bodies would represent an embryoid body derived cell culture that embraces the elements of the invention as claimed.

Applicants submit that it is readily apparent that the EBs of Shambrott et al. (1988) remain EBs, i.e., the properties associated with a non-disaggregated EB, such as having three dimensional morphology or an ability to form teratomas in SCID mice (i.e., an inherent property, see e.g., Gaillard JA. (1976) Experimental Terato-Carcinoma: Behavior of Embryoid Bodies Inoculated into the Abdominal Cavity of Syngenic Mice. *Bull Cancer.* 63(3):341-352), are unchanged.

As recited in the instant specification at page 3, lines 9 and 10, for example, embryoid body derived (EBD) cells do not form teratomas in SCID mice as an inherent characteristic. Further, EBDs are disaggregated, and do not possess three dimensional morphology.

As stated in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987),

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

Shambrott et al. do not teach that the EBs are disaggregated (i.e., do not possess three dimensional morphology) and/or that the EBs have lost the ability to form teratomas. Thus, Shambrott et al. does not teach every element of the instant claims.

Therefore, as every element as set forth in the instant claims is not found in the cited reference, Shambrott et al. does not anticipate the instantly claimed invention.

For the reasons given above, Applicants respectfully submit that the rejection does not apply to the claims, including those as amended, and request that the rejection be withdrawn.

### **III. Rejections Under 35 U.S.C. §103(a)**

A. Claims 1, 3-6, and 8 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Shambrott et al (1998). Applicants traverse the rejection against these claims, including those as amended, for the reasons given below.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).” M.P.E.P. §2143.

As stated above for the §102(b) rejection, Shambrott et al. does not specifically teach that the EBs as described are disaggregated (i.e., do not possess three dimensional morphology) and/or that the EBs have lost the ability to form teratomas. There is no suggestion in the reference itself or in the reasoning that has been offered by the Examiner as knowledge generally available to the ordinarily skilled artisan which cures this deficiency.

Further, there would be no expectation of success, since one of skill in the art would not possess a cell culture with the properties as recited in the claims (e.g., no ability to form

teratomas in SCID mice) in view of the teachings of Shambrott et al. or through the reasoning offered by the Examiner.

Respectfully, the teaching or suggestion regarding the properties of the cell culture of the instant invention would not be apparent in the absence of Applicants' disclosure, and as such, a finding of obviousness in this instance would represent impermissible hindsight (see, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 USPQ 543 (Fed. Cir. 1985)).

Therefore, the Examiner has not met the burden for establishing *prima facie* obviousness. For these reasons, Applicants respectfully submit that the rejection does not apply to the claims, including those as amended, and request that the rejection be withdrawn.

B. Claims 13, 15 and 16 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Shambrott et al (1998). Applicants traverse the rejection against these claims, including those as amended, for the reasons given below.

As stated above, Shambrott et al. fail to teach the elements of the claim from which claims 13, 15, and 16 depend, i.e., the reference does not make obvious the inherent properties of the EBD culture as claimed, which are not shared by the EBs of Shambrott et al. Further, the reasoning offered by the Examiner does not cure this deficiency.

Therefore, the Examiner has not met the burden required for establishing *prima facie* obviousness. Thus, for these reasons, Applicants respectfully submit that the rejection does not apply to the claims and request that the rejection be withdrawn.

**CONCLUSION**

Applicants submit that the pending claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the rejections, and early indication of allowance are requested respectfully. If any questions remain, the Examiner is urged to contact the undersigned below.

No fee is believed due in connection with this Amendment. If any additional fees are due, the Commissioner is hereby authorized to charge any fees that may be required by this paper to Deposit Account No. 50-1355. A duplicate copy of this Transmittal Sheet is attached.

Respectfully submitted,

  
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